NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

FEDERAL TRADE COMMISSION, Plaintiff, v. LANE LABS-USA, INC., CARTILAGE CONSULTANTS, INC., corporations, and I. WILLIAM LANE and ANDREW J. LANE, individuals, Defendants.	**Hon. Dennis M. Cavanaugh** **OPINION** Civil Action No. 00-cv-3174 (DMC)

DENNIS M. CAVANAUGH, U.S.D.J.:

This matter comes before the Court upon motion by Plaintiff, the Federal Trade Commission ("FTC") for a finding that Defendants Lane Labs-USA, Inc. ("Lane Labs"), Andrew Lane, and Dr. I. William Lane (collectively, "Defendants") are in violation of Orders agreed to by the parties and entered by the Honorable William G. Bassler, U.S.D.J. on June 30, 2000. The FTC seeks to have this Court find that Defendants are in contempt as a result, and to fine Defendants twenty-four million dollars and to have any monies levied turned over to the FTC to be disbursed to consumers allegedly injured by Defendants' actions.[1] Beginning on April 20, 2009, this Court conducted an evidential hearing lasting five days. After carefully considering the complete record, and based upon factual findings below, this Court concludes that the FTC has not sustained its burden of proof. Accordingly, the FTC's motion is **denied**.

[1]It should be noted that the alleged injuries consist of consumers paying premium prices as a result of false claims and not for any personal injuries suffered as a result of ingesting Defendants' products. In any event, Defendants challenge the damages amount arguing that the amount proposed by the FTC is excessive and inaccurate.

I. FACTUAL FINDINGS

The FTC's contempt motion arises out of claims made regarding Lane Labs' AdvaCAL and Fertil Male products. Lane Labs USA Inc., founded in 1994 by Andrew Lane is a supplier of dietary supplements. Dr. William Lane, as well as being Andrew Lane's father, is a researcher, educator, and author on the subject of alternative medicine. Dr. William Lane has doctoral degrees in biochemistry and nutrition from Rutgers University. In 2000, Defendants entered into Consent Orders with the FTC in connection with two totally unrelated products (Skin Answer and Benefin). The Consent Orders preclude Defendants from making representations regarding the effect of any health product without being able to support those claims with reliable scientific evidence. Claiming Defendants violated the Orders, the FTC filed this motion on January 11, 2007, seeking to hold Defendants in contempt. Following extensive discovery, this Court conducted an evidentiary hearing over the course of five days commencing on April 20, 2009. The Court also considered pre and post hearing submissions filed on behalf of all parties.

The Hearing

AdvaCAL or "AAACa" is a patented calcium supplement derived from oyster shells that are smelted at extremely high temperatures. The smelting process changes the chemical form of the shells from calcium carbonate to calcium hydroxide and calcium oxide. In addition, small amounts of heated algae ingredient ("HAI") are added to the calcium for increased absorbability into the body. According to Defendants, AdvaCal is the only calcium hydroxide and calcium oxide supplement available in the United States.

Fertil Male is a dietary supplement derived from a Peruvian plant known as "Maca" or Lepidicum meyenni. Defendants claim Fertil Male is a supplement that can improve male fertility parameters.

The FTC's motion is predicated on a number of claims made by Defendants which the FTC believes violate the prior Orders. A representative selection of these claims are:

- AdvaCAL has been "clinically shown to be three times more absorbable than other calciums;"
- AdvaCAL is "absorbed three times better than typical calcium carbonate/coral calcium supplements;"
- AdvaCAL is the "only" calcium that can increase bone mineral density;
- AdvaCAL produced a 3 percent per year increase in bone density "over a period of years;"
- Results from a "group" study demonstrates that AdvaCAL caused a 13.5% increase in bone density over two years;
- AdvaCAL has been shown in clinical tests to increase bone density in the hip;
- In an infomercial for AdvaCAL produced in 2003, Lane Labs included a testimonial from a 25 year old woman named "Michelle C." who claimed that after taking AdvaCAL, her bone density increased by 50% in six months.

Additionally, the FTC challenges four statements made by Dr. Lane regarding AdvaCAL:

- AdvaCAL "is the only calcium I've seen that has been shown over and over to build bone density"
- AdvaCAL "is the only calcium I know that can increase bone density"
- "Most of the supplements out there don't have available, digestible calcium"
- Calcium is so hard that the body "cannot absorb it -like a rock!" "It goes in one end and out the other"

With respect to Fertil Male, the FTC challenges Defendants' general claim that Fertil Male has been "clinically-shown" to increase sperm production, sperm motility, and semen production.

The claims at issue appeared over a number of years, since 2000 for AdvaCAL and 2003 for Fertil Male, in Lane Labs' CompassioNet catalogs, the Lane Labs CompassioNet and product

specific websites, direct mailing packages, national magazines, national trade publications, national publications directed at health care providers, and infomercials that were broadcast and distributed as CD-Roms.

Defendant Andrew Lane testified at length regarding the steps he personally took and efforts taken by others at Lane Labs to ensure compliance with the Orders. Mr. Lane testified that he traveled to meet with researchers and to see how different products were made. Mr. Lane further testified that a process was established to vet every claim in an advertisement and that a file was kept of all substantiation for each advertisement or claim. Mr. Lane explained how at times multiple reports or studies were combined to make a given claim or to produce an advertisement, but that someone with knowledge in the field checked to make sure every advertisement and/or claim was not misleading. The Court found Mr. Lane to be forthcoming and credible, and considers his testimony to be evidence of the efforts undertaken by Defendants to comply with the Orders.

At the hearing, the FTC offered two expert witnesses, Dr. Robert P. Heaney regarding AdvaCAL and Dr. Craig Niederberger regarding Fertil Male. The Defendants offered two experts witnesses as well, Dr. Michael Frank Holick regarding AdvaCal and Dr. Machelle M. Seibel regarding Fertil Male. The Court will address each of these witnesses individually.

Dr. Robert P. Heaney

Dr. Heaney is a physician trained as an internist-endocrinologist and is on the faculty of Creighton University in Omaha, Nebraska. Dr. Heaney is the principal scientist in Creighton's Osteoporosis Research Center. Dr. Heaney has been on Creighton University's faculty for fifty-two years. At the time of the hearing Dr. Heaney held the administrative position of Interim Vice President for Health Sciences at Creighton. Dr. Heany held this position until August 3, 2009, when

he was named Creighton University's Vice President of Research. The Court recognized Dr. Heaney as an expert in the field of calcium research.

Dr. Heaney was originally hired by Lane Labs prior to the FTC's contempt claims, to assess AdvaCAL and specifically, to compare the absorbability of calcium from AdvaCAL to Citracal,[2] another calcium supplement. Dr. Heaney applied the pharmacokinetic method which measures the amount of calcium absorbed from the intestine into the bloodstream. In studying the data produced from his comparative study, Dr. Heaney concluded that AdvaCAL is absorbable and that it is a good source of calcium. Dr. Heaney further concluded that AdvaCAL is inferior to Citracal by approximately twenty percent. Dr. Heaney testified that absorbablility is the critical measure because there is currently no means known to science for a calcium source that is not absorbed as well as another to nevertheless cause superior results. After communicating his conclusions to Lane Labs Dr. Heaney proposed a larger study. Lane Labs decided not to fund the larger study. Subsequent to working with Lane Labs, Dr. Heaney was retained by the FTC to review Lane Labs' AdvaCAL advertising and to testify as an expert in this matter.

Dr. Heaney testified that it is general practice when comparing one product to another to ensure two components: "randomization on the one hand, and complete follow-through or obtaining the information on all the subjects that you have randomized to the treatments." Dr. Heaney added that "different products have to be tested side by side in the same population." Dr. Heaney was asked his opinion as to whether the evidence provided by Lane Labs in support of its claims pertaining to AdvaCAL provided substantiation. The witness responded that in his opinion, Lane Labs' claims were not substantiated by competent and reliable scientific evidence as defined in the

[2]Citracal is brand-name product that contains calcium citrate which is a calcium salt often used as a calcium supplement.

Orders. Dr. Heaney further discussed formulation and how changing the formulation of a product effects the relevance of information based on the old formulation. Specifically, Dr. Heaney was asked about and discussed inert excipients, which, although not active ingredients, can change the effect of active ingredients. Dr. Heaney also discussed individual reports and studies relied upon by Lane Labs and explained why he believes these studies and reports do not constitute reliable scientific evidence. The Court notes that Dr. Heaney, a very capable researcher, was critical of most studies and held these studies to a standard that would be difficult to obtain.

On cross-examination by defense counsel, Dr. Heaney acknowledged that a good calcium source can be expected to produce the benefits of calcium and that AdvaCAL is a good source of calcium. Specifically, Dr. Heaney testified that calcium literature and studies about other forms of calcium can be used to support claims for AdvaCAL. Dr. Heaney testified that if he had the original data for any study on calcium or osteoporosis he could "almost certainly" find a flaw with that study. Dr. Heaney additionally testified that the half life for medical publications is approximately four or five years. Meaning, after four or five years there is superceding, additional, better, or contrary information. Dr. Heaney agreed that once an article, notwithstanding the fact that he might disagree with it, has been published in a peer-reviewed publication, such an article can provide substantiation. Dr. Heaney explained that a company could rely on the facts of a publication but not necessarily the authors' opinion. Dr. Heaney further stated that a company wishing to rely on the facts of a study must also analyze whether the study was conducted properly. He explained that a professional could and should perform this service as a consultant. Dr. Heaney stated that he would not fault a manufacture who took a peer reviewed study, tried to determine if the study was conducted properly, and then relied on that study. The Court finds these views somewhat unreasonable.

On redirect, Dr. Heaney testified that "the New England Journal [of Medicine], which would

be considered one of the premier journals for the publication of clinical results whether you live in New England or the rest of the U.S. or Europe, for that matter, published a communication from the editors looking back over their own experience with peer-reviewed publications and [state] that something on the order of [50%] of the papers [printed] in retrospect have been significantly flawed."

Dr. Craig Stuart Niederberger

Dr. Niederberger is a physician and researcher in the area of andrology (male reproductive medicine) and urology. Since in 1993, Dr. Niederberger has been on the faculty of the College of Medicine and the College of Engineering in the Department of Bioengineering at the University of Illinois at Chicago, where he is currently the Chairman of the Department of Urology. Dr. Niederberger was recognized by the Court as an expert in the field of urology.

Dr. Niederberger opined that there is no evidence to support Lane Labs' claim that Fertil Male optimizes male fertility. Dr. Niederberger explained his understanding of what constitutes "competent reliable scientific evidence." Dr. Niederberger implied that evidence relied upon must result from tests that are objective/non-biased. Dr. Niederberger stated that bias is removed by incorporating randomization and a placebo.

Dr. Niederberger explained how he assesses fertility. He testified that semen analysis is an imperfect test but is the principle basic test. Semen has several components, the volume of the ejaculate, the amount of liquid in the ejaculate, the sperm count, and the motility (how the sperm moves) of the sperm. Dr. Niederberger also discussed the relevancy of sperm morphology which compares what sperm actually looks like to what it should look like. Dr. Niederberger testified that he is aware of five studies that discuss the effect of Maca on fertility; a 2001 study in the Asian Journal of Andrology using rats as subjects, a 2001 study on nine men, a 2004 rat study in the

Journal of Endocrinology, an unpublished manuscript, and a doctoral thesis. While stating the obvious, that in normal circumstances a man has to be able to have sex to impregnate a women, Dr. Niederberger explained that sexual activity or impotency is a separate and distinct issue from infertility. Dr. Niederberger explained why he believes that the five studies mentioned above do not constitute competent reliable scientific evidence for the proposition that Fertil Male promotes male fertility. Dr. Niederberger based his opinion on criticisms that the studies were under powered (did not have enough participants), utilized inaccurate measuring techniques, and/or the fact that the test subjects in two of the studies were rats as oppose to humans.

Dr. Niederberger further testified that if a dietary supplement caused no harm but could do some good he would have no problem with a doctor advising a client to take the supplement. Dr. Niederberger added that Maca has not been shown to have a benefit and that he believes there is some evidence that Maca might cause harm so he would not support advising a client to take Maca based on the above rational. Dr. Niederberger stated that he would want the best evidence that an agent improves fertility before he would advise a patient to ingest the agent.

Dr. Michael Frank Holick

Dr. Holick is a professor of medicine, physiology, and biophysics at the Boston University Medical Center. He is Director of the General Clinical Research Center and the Bone Health Care Clinic. Dr. Holick holds both a Ph.D. and an M.D. Dr. Holick was qualified as an expert in calcium, vitamin D metabolism, and bone health. He was called as a defense expert witness.

Dr. Holick testified that the studies he reviewed dealing with AdvaCAL or its active ingredients used research structures discussed by Dr. Heaney, randomization and placebo/control groups. Dr. Holick discussed many of the documents presented by Lane Labs and criticized by Dr. Heaney. Dr. Holick provided a different interpretation of these documents. Dr. Holick testified that

while researchers do not like to see test subjects who initially took part in a study not complete the study or rather "dropout" of the study group, the effect of dropouts on a study can be dealt with by statistical analysis and by asking the author to explain why a subject dropped out of the study group. Dr. Holick explained how research not specifically on point with a claim can still be used to substantiate that claim. For example, if you have a study that says a product will increase bone density, that study can be used as a surrogate to substantiate a claim that the product will reduce risk of fracture because better bone density reduces risks of fractures.

Dr. Holick testified that Dr. Heaney's comparative study of AdvaCAL and Citracal was flawed because of the use of 25-hydroxyvitamin D. Dr. Holick further testified that Dr. Heaney's data does not necessarily mean that Citracal is absorbed better than AdvaCAL as concluded by Dr. Heaney. Dr. Holick testified that in his opinion there is reliable scientific evidence that AdvaCAL reduces fracture risk better than calcium carbonate and that AdvaCAL is better absorbed or more bioavailable than calcium carbonate. Dr. Holick testified that while dramatic bone density increases over a relatively short period of time resulting from regulating a patient's calcium and vitamin D levels is unusual, he has seen it occur. Dr. Holick explained that he would want to know more about the medical condition of the patient, but he would not dismiss a dramatic increase in bone density as error.

Dr. Machelle Seibel

Dr. Seibel is a medical doctor and is a professor at the University of Massachusetts Medical School. Before holding this position Dr. Seibel was on the faculty of Harvard Medical School for nineteen years where he oversaw the reproductive endocrinology labs and was Chief of the Division of Reproductive Endocrinology. Although Dr. Seibel is not a urologist, he has treated male patients for infertility. Dr. Seibel serves part-time as the Medical Director for a publicly traded company.

In his capacity as Medical Director, Dr. Seibel is responsible for the supplements that the company produces. As a result of the various positions Dr. Seibel holds, he has reviewed many studies. Dr. Seibel was qualified as an expert regarding fertility.

Dr. Seibel discussed several studies offered by Lane Labs to substantiate its claims pertaining to Fertil Male. Dr. Seibel testified to the relevancy of studies where the subjects are rats and the use of randomization. He stated that while having a placebo group is optimal, it is not uncommon for studies in this area to not use placebo groups. Dr. Seibel explained why he believes that the studies offered by Lane Labs are reliable competent scientific substantiation of Lane Labs' claims regarding Fertil Male. Dr. Seibel stated that "half of the things on the shelf have no studies..." and that it is "so unusual to have [] studies that it is refreshing." Dr. Seibel testified that he is of the opinion that there is competent and reliable scientific evidence that Fertil Male is clinically shown to promote sperm count, motility, and production. Dr. Seibel further testified that he has no hesitation about offering Fertil Male to his patients if other treatments are not working.

All four expert witnesses were credible and knowledgeable in their respective fields of expertise. This Court however, was more impressed by the testimony of Defendants' experts because their testimony and approach to the subject matter seemed more reasonable and in accordance with the Consent Orders. In considering the testimony offered by all of the experts the difference between the FTC's experts and the Defendants' experts came down to a difference of opinion - not necessarily matters of right and wrong. Defendants clearly offered support and substantiation for the claims regarding their products.

II. STANDARD OF REVIEW

A. Civil Contempt

"The exercise of the power to find and to punish for contempt is [] discretionary, and should be undertaken with the utmost sense of responsibility and circumspection." Thompson v. Johnson, 410 F. Supp. 633, 640 (E.D. Pa. 1976), aff'd 556 F.2d 568 (3d Cir. 1977). For a party to be held in civil contempt, a plaintiff must show that "(1) a valid court order existed, (2) the defendant had knowledge of the order, and (3) the defendant disobeyed the order." John T. v. Delaware County Intermediate Unit, 318 F.3d 545, 552 (3rd Cir. 2003) (quoting Harris v. City of Philadelphia, 47 F.3d 1342, 1326 (3rd Cir. 1995)). The burden then shifts to the alleged contemnors to show why they were unable to comply with the order. FTC v. Affordable Media, LLC, 179 F.3d 1228, 1239 (9th Cir. 1999), cert. denied *sub nom* Lawson v. FTC, 534 U.S. 1042 (2001); In re Affairs with a Flair, 123 B.R. 724, 727 (Bankr. E.D. Pa. 1991).

To establish contempt the movant bears the burden of proving by clear and convincing evidence that the respondent violated a court order. Roe v. Operation Rescue, 54 F.3d 133, 137 (3d Cir. 1995). This standard is not satisfied unless the evidence "produce[s] in the mind of the trier of fact a firm belief or conviction as to the truth of the allegations sought to be established, evidence so clear, direct and weighty and convincing as to enable [a court] to come to a clear conviction without hesitancy, of the truth of the precise facts." U.S. v. Askar, 222 Fed. Appx. 115, 119 (3d Cir. 2007) (quoting In re Jobes, 108 N.J. 394 (1987)). Where there is any reason to doubt the wrongfulness of the respondents conduct, a court should not find contempt. Paul T. V. Delaware County Intermediate Unit, 318 F.3d 545, 552 (3d Cir. 2003). Willfulness is not an element of contempt, nor does evidence of good faith bar a conclusion that a defendant acted in contempt.

Robin Woods, Inc. v. Woods, 28 F.3d 396, 399 (3rd Cir. 1994).

Moreover, substantial compliance with a court order is a defense to civil contempt. "[A] defendant may not be held in contempt as long as it took all reasonable steps to comply." Harris v. City of Philadelphia, 47 F.3d 1311, 1324 (3d Cir. 1994) (citations omitted). If a respondent "has made in good faith all reasonable efforts to comply" with a court order, "technical or inadvertent violations of the order will not support a finding of civil contempt." Raza v. Biase, 2008 U.S. Dist. LEXIS 20526 *12 (D.N.J. March 14, 2008).

III. DISCUSSION

The first two elements of civil contempt are uncontested in this case. The Consent Orders were and are valid and controlling. Andrew Lane testified that he knew of the Orders, posted the Orders easily viewable in his office, and distributed the Orders to senior members of his staff. The third element, whether the Defendants' disobeyed the Orders, and the defense of Substantial Compliance are the dispositive issues in this case.

A. The Consent Orders

The FTC asserts that Defendants violated Sections III, IV and IX of the Consent Orders. Section III requires Defendants, in making claims about the health benefits of a product, to possess competent and reliable scientific evidence that substantiates their claims. "Competent and reliable scientific evidence" is defined in the Orders as: tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate results. Section IV bars Defendants from misrepresenting "the existence, contents, validity, results, conclusions, or interpretations of any test, study or research." Section 5

of the FTC Act provides a standard for determining whether a statement is deceptive. The Act details that the net impression created by the advertisement as a whole is the controlling factor. "The impression created by the advertising, not its literal truth or falsity, is the desideratum." American Home Products v. FTC, 695 F.2d 681, 687 (3rd Cir. 1982). Section IX of the Consent Orders requires Defendants to maintain adequate records.

B. Section III

The FTC argues that Defendants did not rely upon competent reliable scientific evidence. In support of this contention, the FTC offered two expert witnesses, Dr. Heaney who testified regarding AdvaCAL and Dr. Niederberger who testified regarding Fertil Male. In response, Lane Labs presented two experts, Dr. Holick regarding AdvaCAL and Dr. Seibel regarding Fertil Male. Both of Defendants' witnesses testified that Lane Labs did have competent reliable scientific evidence to support its claims. As stated above, the Court was more swayed by the defense experts.

The result of both the FTC's and Defendants' considerable efforts is that this case has become a battle of the experts. The Court found all four of the above identified experts to be credible and their testimony to be informative. Of critical importance is the fact that Dr. Heaney testified that AdvaCAL is a good source of calcium and that Dr. Niederberger merely questioned what can be determined from the studies pertaining to Maca, the active ingredient in Fertil Male. Neither of the FTC's experts stated that the supplements marketed by Lane Labs are not effective[3] or constitute a health risk to the public. Further, Lane Labs' experts testified that they believe that

[3]The Court recognizes that Dr. Niederberger testified that Maca, the active ingredient in Fertil Maile, has not been shown to have a benefit. Dr. Niederberger's statement, however, is predicated upon his belief that the substantiation provided by Defendants is inconclusive and not upon research undertaken by Dr. Niederberger personally or research evidencing that Maca is ineffective.

the supplements do indeed have beneficial effects and that they would not hesitate in advising their clients to take them when appropriate.

In support of its motion, the FTC engaged in significant discovery and presented a nuanced case that delved into the details of every piece of substantiation offered by Lane Labs. While the FTC's experts identified several questionable aspects to the studies and reports offered by Lane Labs, Lane Labs' experts explained why these concerns do not negate the value of the studies and reports. Additionally, the Court considers the fact that Lane Labs did what they were suppose to do, what Dr. Heaney suggested a lay person should do. That is, before relying on scientific articles Lane Labs sought expert advice. This is not a case of a company making claims out of thin air. Of concern to the Court is the notion that a lay person should have to do more than can reasonably be expected when confronted with both reliable and/or peer reviewed studies and articles. Lane Labs found a product and obtained scientific evidence that the product is efficacious. Lane Labs then consulted experts who opined that the research supporting the product and the product itself were good. Lane Labs acted in accordance with the spirit of Judge Bassler's Orders.

In a further effort to comply with the Consent Orders, Lane Labs submitted to the FTC multiple voluminous compliance reports between 2001 and 2006[4]. Lane Labs under took efforts to verify the claims it had made and intended to make about the products at issue. Additionally, Lane Labs hired a compliance officer, Jennifer Morganti from 2001 to 2004. During the hearing, Lane

[4]It has not gone unnoticed by the Court that the Defendants submitted substantiation and multiple compliance reports in a timely manner during the years of 2001 through 2006, as required by the Consent Orders. By submitting compliance reports, Defendants basically informed the FTC of their plans in advance. In spite of these submissions, the FTC never contacted or advised Defendants of a compliance issue until January 12, 2007. In the Court's view, Defendants acted reasonably and appropriately in assuming that they were in compliance since they heard nothing to the contrary for years.

Labs provided credible expert testimony in support of both the claims it made and the substantiation it provided in support of those claims. As a result, the Court is satisfied that Lane Labs complied with Section III of the Consent Orders.

C. Section IV

The primary issue here is what impression was created by the advertising distributed by Lane Labs. American Home Products, 695 F.2d at 687. The FTC presented many pieces of advertising that were created and circulated by Defendants. These advertisements, as could be expected, strongly encouraged consumers to buy Defendants' products.

During the hearing, the FTC provided evidence that some of the statements contained in the advertising claims made by Defendants were incorrect. Mr. Lane admitted during his testimony that some things slipped through the cracks and that errors were made over a number of years. This notwithstanding, the impression created by Defendants' advertisements is that both supplements are good products that will most likely help the people who take them. While the FTC believes this is a false impression, as stated above, even the FTC's experts do not go as far as to say that the products do not work and Dr. Heaney acknowledged that AdvaCAL is a good source of calcium. Moreover, Defendants provided credible medical testimony that the products in question are good products and could have the results advertised by Defendants. Therefore, the FTC has not carried its burden of demonstrating that Lane Labs has created a false impression in violation of Section IV of the Consent Orders.

D. Section IX

The FTC argues that Defendants have not complied with their obligation to maintain records regarding all of the claims they made in their advertisements. While this issue was not initially

identified in the FTC's trial brief, at trial it became evident that an early poster presentation obtained and relied upon by Defendants and a version of an advertisement were not submitted to the FTC as required by the Consent Orders. Given the amount of material that has been kept, and the fact that the poster was created and obtained by Lane Labs prior to the issuance of the Orders, it appears that Defendants have made every reasonable effort to comply with the record keeping requirement and certainly did not intentionally discard covered material.

E. Substantial Compliance

Defendants argue alternatively that even if there are technical issues regarding their actions, they have made a good faith effort to substantially comply with the Consent Orders. In response, the FTC argues that the issues it raises are not technical or inadvertent and that Defendants have not taken all reasonable steps to comply with the Consent Orders and therefore, Defendants cannot argue substantial compliance.

As detailed above, the Defendants have undertaken considerable efforts to learn about the products at issue and to make claims that they believed were supported by credible evidence. More to the point, Defendants have exerted considerable effort to comply with the Consent Orders including seeking expert advise and hiring a compliance officer. Based on the evidence offered by the FTC, it is evident that the materials relied upon by Defendants are in hindsight not perfect. This however, does not negate Defendants' efforts to obtain good information and expert advice.

The application of the substantial compliance defense is further supported by Defendants submission of compliance reports for years which the FTC ignored until preparing to commence this action. Defendants submitted lengthy reports which evidence the fact that they exerted great effort to try and comply with the Orders.

Moreover, Defendants' submissions raise a significant issue of fundamental fairness. The FTC addresses this issue by arguing that Defendants are trying to avail themselves of the defense of laches. The FTC argues that allowing Defendants to rely upon this defense would turn the Orders on their head because it would allow Defendants to "wantonly violate the Orders unless and until the FTC took action." The FTC further argues that the laches defense fails as a matter of law because "[a]s a general rule laches or neglect of duty on the part of officers of the Government is no defense to a suit by it to enforce a public right or protect a public interest." Nevada v. United States, 463 U.S. 110, 141 (1983); Mudric v. Atty Gen. of the United States, 469 F.3d 94, 99 (3d Cir. 2006).

The FTC mis-conceptualizes the issue. The issue here is not that Defendants broke the law and the FTC did nothing to stop it. At issue is whether Defendants were compliant with the Consent Orders. Defendants thought they were compliant and undertook significant efforts to be compliant. In the Court's view, Defendants' voluminous submissions to the FTC which detail all of the substantiation Defendants obtained along with Defendants' other actions such as hiring a compliance officer, justify Defendants' belief that they were compliant with the Orders. In this Court's opinion, to tell Defendants that their efforts were not good enough years after not advising them of any compliance issues is disingenuous and is highly relevant to the inquiry into whether Defendants should have done something different in the first instance. Moreover, the Court notes that there has been no physical harm to the public. The FTC seeks to have the Court fine Defendants to allow the FTC to distribute the monies collected to consumers to cure consumer injury resulting from alleged over payment for Defendants' products. Despite the FTC's claims, the FTC provides no evidence that consumers have complained that they were physically harmed by the use of either supplement. This compounds the fundamental fairness issues in this case.

The issues raised by the FTC in this action are subject to interpretation. The differences between the expert opinions evidences this fact. The Orders do not specifically require that which the FTC is arguing was and is required. If the Defendants were not able to present justification for its claims and actions, then the FTC's laches argument might be relevant, however, Defendants have support for their position. Given that Defendants obtained and provided scientific evidence that experts in the field said could be relied upon and they were never told otherwise, it would be fundamentally unfair to now say that they have been violating the Orders and therefore must pay a prohibitive penalty. The facts presented by Defendants and the failure of the FTC to timely consider Defendants' compliance reports suggest that Defendants took all reasonable steps to substantially comply with the Consent Orders.

IV. CONCLUSION

For the reasons stated, the FTC's motion for a finding of contempt is **denied**. An appropriate Order accompanies this Opinion.

S/ Dennis M. Cavanaugh
Dennis M. Cavanaugh, U.S.D.J.

Date: August 10, 2009
Orig.: Clerk
cc: Counsel of Record
The Honorable Mark Falk, U.S.M.J.
File